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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/736,863

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Robert Emmett Atkinson

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/736,863	Applicant(s) ATKINSON ET AL.	
	Examiner MICHAEL KAHELIN	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29,30,32,34-36,38,40-44 and 46-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29,30,32,34-36,38,40-44 and 46-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/19/2009 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 32, 38, 41-44, 46, and 49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner was unable to find support in the originally-filed disclosure for the closed transition phrase "consisting of." The discussion of the "braid" feature (at, e.g., paragraph 031) lacks disclosure of excluding other elements from the tether.

Any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. Any

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claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement (See MPEP 2173.05(i)).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 29, 34, 35, 40, 41, 43, and 46-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osypka (US 6,738,674, hereinafter "Osypka") in view of Huepenbecker et al. (US 6,289,251, hereinafter "Huepenbecker").

7. In regards to claims 29, 34, 35, 41, and 43, Osypka discloses the essential features of the claimed invention including an electrical lead (312) with a lumen extending therethrough (Fig. 7) and a distal exit port distal of the one or more distal

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electrodes (322a and 322b); and an anchoring device (Fig. 11) including a self-expanding anchor (60) and extending proximally from the anchor, extending through the proximal entry port of the lead (Fig. 7), and wherein the anchoring device is longitudinally movable in the lumen of the lead such that the lead may be advanced over the anchoring device (Fig. 9). Osypka does not disclose that the anchoring device includes a tether consisting of a polymeric cord tied in a knot to the anchor.

Huepenbecker teaches an anchoring device consisting of a tether tied in a knot to the anchor (Fig. 4, col. 3, lines 37-40 and col. 4, lines 19-26) to provide the predictable result of reinforcement in devices such as leads without the disadvantage of an overall increase in lead body diameter (col. 1, lines 59-62). The Examiner's position is that substituting Huepenbecker's reinforced lead structure for the coronary sinus lead of Osypka would have been a simple substitution of known elements to obtain the predictable results of a coronary sinus lead that is stronger due to additional reinforcement. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Osypka's invention by providing a reinforced inner lead with a tether tied in a knot to the anchor to provide the predictable result of additional reinforcement without the disadvantage of an overall increase in lead body diameter. Please note that the substitution of Huepenbecker's reinforced lead for Osypka's coronary sinus lead (as shown in, e.g., Figure 7 of Osypka) would necessarily result in a tether that extends through the proximal entry port of the outer lead as the reinforcement member extends the entire length of the inner lead (Huepenbecker, col. 1, line 60).

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8. In regards to claims 40 and 46, the tether is detachable from the lead using, *e.g.*, scissors or wire cutters.

9. In regards to claims 47-49, the lead is an implantable pacing lead (col. 1, line 15).

10. Claims 30, 36, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osypka in view of Huepenbecker as applied to claims 29, 35, and 41 above, and further in view of Hine et al. (US 2003/0204231, hereinafter "Hine").

Osypka's modified invention discloses the essential features of the claimed invention, including a connector for limiting longitudinal movement between the lead and the anchoring device (46), but does not expressly disclose that the connector is disposed in the lumen of the lead adjacent the tether. Hine teaches a similar telescoping lead/tether configuration wherein the system includes a connector disposed in the lumen of the lead adjacent the tether (element 516 and par. 0036) to provide the predictable results of securely maintaining relative position and spacing of the two members while also reducing fluid intrusion. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify Osypka's invention by providing the connector of Hine to provide the predictable results of securely maintaining relative position and spacing of the two members while also reducing fluid intrusion.

11. Claims 32, 38, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osypka in view of Huepenbecker as applied to claims 29, 35, and 41

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above, and further in view of Williams et al. (US 6,516,230, hereinafter "Williams").

Osyпка, as modified by Huepenbecker above, discloses the essential features of the claimed invention including a tether consisting of a "stranded cord" (see Huepenbecker, col. 3, lines 37-40 and Fig. 4, element 50). Osypka's modified invention does not disclose a tether that consists of a braid. However, Williams teaches that it is known in the art to provide braided tether cords (col. 3, lines 29-35) to provide the predictable results of a strong and flexible reinforcing member that conforms to the circular cross-section of a lead. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify Osypka's invention by providing a braided tether cord to provide the predictable results of a strong and flexible reinforcing member that conforms to the circular cross-section of a lead.

Response to Arguments

12. Applicant's arguments with respect to claims 29, 30, 32, 34-36, 38, 40-44, and 46-49 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment. Please note the new grounds of rejection in view of the previous art of record (Osyпка and Huepenbecker). The previous Office Action proposed a modification of Osypka wherein the anchor of Osypka is attached by knot to the lead structure of Osypka. The instant rejection relies on a modification of Osypka wherein the inner lead of Osypka is replaced by the reinforced lead/anchor configuration of Huepenbecker (*i.e.*, using the "reinforced"-type lead of Huepenbecker instead of merely attaching the anchor of Osypka to the lead of Osypka by knot).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762